# DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

# **Centers for Disease Control and Prevention National Center for Injury Prevention and Control**

# **Board of Scientific Counselors Closed Session**



Eleventh Meeting June 13-14, 2013 Summary Report

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# AGENDA DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE BOARD OF SCIENTIFIC COUNSELORS (BSC)

Centers for Disease Control and Prevention (CDC)
National Center for Injury Prevention and Control (NCIPC)
Eleventh Meeting

June 13th, 2013 4770 Buford Highway Chamblee Campus, Building 106, Conference Room 1B Atlanta, GA 30341

June 14, 2013 Century Center, 1825 Century Boulevard, NE Room 1042-1B Atlanta, GA 30345

#### **Summary Proceedings**

The eleventh meeting of the National Center for Injury Prevention and Control (NCIPC) Board of Scientific Counselors (BSC) took place on Thursday, June 13 and Friday, June 14, 2013. The BSC met in closed session for secondary review, in accordance with the Privacy Act and the Federal Advisory Committee Act (FACA), on Friday, June 14, 2013. Dr. Carolyn Cumpsty Fowler served as chair.

#### Friday, June 14, 2013: CLOSED TO THE PUBLIC

#### Opening / Roll Call

Carolyn J. Cumpsty Fowler, PhD, MPH
Chair, National Center for Injury Prevention and Control Board of Scientific Counselors
Assistant Professor, Johns Hopkins University
School of Nursing and Bloomberg School of Public Health

**Dr. Fowler** called the second day of the eleventh meeting of the NCIPC BSC to order at 8:30 am on Friday, June 13, 2014. She noted that the day's agenda had been revised slightly.

**Mrs. Tonia Lindley** conducted a roll call of BSC members and federal liaisons. A quorum of BSC members was present. Those present in the room and on the telephone introduced themselves. A listing of those present is provided with this document as Attachment A.

#### **Federal Advisory Committee Orientation**

Gwendolyn H. Cattledge, PhD, MSEH
Deputy Associate Director for Science
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
Designated Federal Officer, NCIPC BSC

**Dr. Cattledge** greeted the group and began the BSC's Federal Advisory Committee Orientation. Members of the BSC are appointed by the Secretary of the US Department of Health and Human Services (HHS), and as such, are subject to rules and regulations. The Orientation is one of the requirements of FACA members. The training was turned over to Ms. Demetria Gardner and Mr. Terry Wheeler from the CDC MASO Office.

#### **Overview: Federal Advisory Committee Act of 1972**

Demetria Gardner
Committee Management Specialist
Management Analysis and Services Office
Centers for Disease Control and Prevention

**Ms. Gardner** provided the BSC with an overview of the Federal Advisory Committee Act (FACA), which provides the legal foundation for establishing and managing federal advisory committees. Congress determined that advisory committees are a useful and beneficial means of furnishing expert advice, ideas, and diverse opinions to the federal government. FACA ensures that new advisory committees are established only when they are determined to be essential. The act also ensures that committees provide advice that is free of undue influence and open to the public. Standards and uniform procedures govern all administrative aspects of FACA committees. Congress and the public have knowledge of the purpose, membership, activities, and costs associated with the committees. Advisory committees terminate when they have fulfilled the purposes for which they were established.

FACA specifically defines oversight and management responsibilities. Each standing committee of the Senate and House of Representatives reviews the activities of each advisory committee under its jurisdiction to determine whether the committee should be abolished or merged with any other committee; the responsibilities of the committee should be revised; and the committee performs a necessary function that is not already being performed.

Through Executive Order, the President delegated to the Administrator of the General Services Administration (GSA) all the functions vested in the President by FACA. An annual report to Congress is prepared by the Administrator for the President's consideration and transmittal to Congress. GSA monitors and reports compliance with FACA to the Executive Branch. GSA also provides written guidance and FACA training. Additionally, agency heads establish uniform administrative guidelines and management controls for advisory committees that are consistent with directives from GSA. Agency heads also designate an Advisory Committee Management Officer who, in consultation with agency leadership, exercises control and supervision over the advisory committees established by the agency and maintains and ensures public accessibility.

Federal advisory committees may be established by mandate or at the discretion of an agency. Mandated committees are authorized by statute or by the President by Executive Order. Discretionary committees are established when an agency determines a need for advice and recommendations from a federal advisory committee and has consulted with GSA and provided notice to the public of its intent to form the committee. The purpose of the committee is defined in a charter. The agency designates a federal official to serve as the Executive Secretary for the Designated Federal Officer (DFO). The DFO is familiar with the matters under consideration by the committee. The DFO's responsibilities include approving meeting agendas and sharing notices of meetings in the *Federal Register*.

The role of a federal advisory committee is to provide federal officials and the nation with expert information and advice on a broad range of issues affecting federal policies and programs. It also allows the public the opportunity to participate actively in the federal decision-making process. Federal advisory committee membership must be balanced in the points of view represented and the functions to be performed by the committee. The membership of the committees includes Special Government Employees (SGEs), who are private citizens appointed to the committees based on their expertise. They are subject to the "Standards of Ethical Conduct for Employees of the Executive Branch." Committees may also include *ex officio* members, federal officials who represent their agencies as subject matter experts (SMEs). Committees may also include liaison representatives that represent special interest groups, organizations, or affected populations.

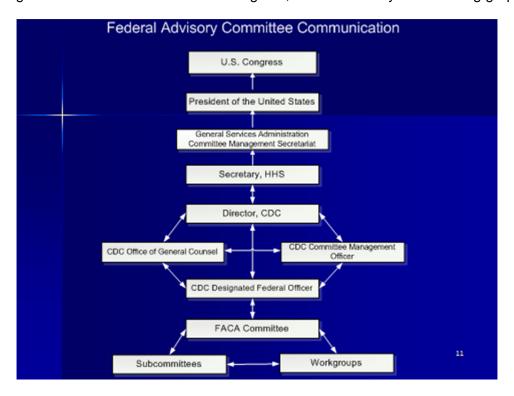
FACA outlines requirements for holding federal advisory committee meetings, including the following:

A public notice announcing the meeting must be published in the Federal Register. The
notice includes the purpose of the meeting, a summary of the agenda, times and locations
for the meeting, and contact information.
The DFO must approve the agenda and be present at committee meetings.
Members of the public must be given the opportunity to speak or file a written statement.
Detailed minutes must be kept and made available to the public.
Official records generated for or by an advisory committee must be retained for the duration
of the advisory committee. Upon termination of the committee, the records must be
processed in accordance with the Federal Records Act and regulations issued by the
National Archives and Records Administration (NARA).

Federal advisory committees may form subgroups to perform special tasks. These subgroups can be subcommittees or workgroups. A subcommittee consists of at least one member of the parent advisory committee. That member reports directly to the parent committee and is not subject to the provisions of FACA; however, Centers for Disease Control and Prevention (CDC) policy requires that subcommittees comply with FACA. Subcommittee recommendations must be deliberated on by the parent committee. A workgroup consists of at least two members of the parent committee or subcommittee and also reports to the parent committee. A workgroup is not subject to the procedural requirements of FACA. A workgroup cannot bring forth any advice or recommendations; rather, it is convened to gather and analyze information, conduct research, and analyze issues and facts.

The US has utilized FACA committees to provide significant recommendations to the President of the United States, federal government agencies, and the nation on a variety of issues. One example is the Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction. This commission was formed in response to the events of September 11, 2001. CDC has also utilized FACA committees in similar fashion. For instance, the Advisory Board on Radiation and Worker Health is CDC's only Presidential Advisory Committee. It provides advice on the development of guidelines, scientific validity, and the quality of dose reconstruction efforts and possible radiation exposures of employees at US Department of Energy (DOE) facilities.

When an advisory committee has deliberated and voted on recommendations, those recommendations become the product of the committee and are forwarded through the agency to the Director of CDC and the Secretary of HHS. Communication from the committee then flows through GSA to the President and to Congress, as illustrated by the following graphic:



FACA ensures that advice rendered to the Executive Branch by advisory committees and their subgroups is both objective and accessible to the public. The act also formalizes a process for establishing, operating, overseeing, and terminating these advisory bodies.

#### **Discussion Points**

**Dr. Fowler** asked that the slides be made available to the BSC. **Ms. Gardner** replied that she would forward the slides.

#### **Federal Advisory Committee Management Training Course**

Mr. Terry Wheeler **Conflict of Interest Specialist Federal Advisory Committee Management Branch Management Analysis and Services Office Centers for Disease Control and Prevention** 

Mr. Wheeler provided the BSC with an overview of the ethics rules for SGEs serving on CDC's federal advisory committees. The overview was based on content developed by the Office of Government Ethics (OGE) regarding ethics regulations as they apply to SGEs. The training fulfilled the requirement for SGEs to complete an ethics orientation within 90 days of their appointment and then annually thereafter.

The SGE category was created by Congress to apply an important, but limited, set of conflict of interest (COI) requirements to a group of individuals who provide important, but limited, service to the federal government. SGEs provide temporary service to the government and are often recruited because they provide outside expertise or perspectives that might be unavailable among an agency's regular employees. SGEs generally serve as advisory committee members, individual experts, or consultants. Some serve on boards or commissions.

For the purpose of COI and ethics rules, SGEs are government employees. It is important to distinguish between SGEs from regular government employees and from persons who are not government employees at all. For example, representatives from interest groups who serve on advisory committees and independent contractors are neither SGEs nor regular government employees. This distinction is important because SGEs are subject to less restrictive COI and ethics requirements than regular government employees, but more restrictive requirements than non-employees, who are generally not covered by COI laws.

In order to protect the public trust, it is necessary to ensure that government employees uphold the highest ethical standards. One of the ways to assure that these standards are upheld is by the collection and review of financial disclosure information to assess potential COI. SGEs who are members of CDC's federal advisory committees file a confidential financial disclosure report, which is not available to the public. CDC utilizes the Army Financial Disclosure Management System (FDM) for filing this confidential report. This online system for filing the OGE-450 is similar to income tax preparation software and includes questions, prompts, and resources to answer filing questions.

The financial disclosure form provides information in such areas as assets, income, liabilities, agreements and arrangements, and outside positions. For the purposes of this form, "outside positions" are non-federal positions. SGEs must also furnish their most recent curriculum vita (CV) or resume and a Foreign Activities Questionnaire, or HHS-697. This year, the CDC-1450, "Research Support and Project Funding Report," is also required.

After the OGE-450 is filed, CDC ethics officials, MASO, and the DFO review it for completeness and accuracy. If the report is complete and indicates no COI, then the officials sign it. There may be follow-up questions or the need for additional information concerning the form. Ethics officials take SGEs' duties and positions into account as they review the reports for possible COI.

One of the most important purposes of the ethics rules and laws is to help employees avoid COI. Agency officials regularly deal with COI statutes found in Chapter 11, Title 18 of the US Code. Many of these statutes allow for special provision or treatment of SGEs. One of the most important codes is Section 208 of Title 18, which pertains to financial conflicts of interest. This statute prohibits all employees, including SGEs, from participating in any particular government matter that will have a direct and predictable effect on their financial interests. It also prohibits employees from acting in government matters that will affect the financial interests of others with whom they have certain relationships. These relationships include spouse; minor child: general partner; and organization in which the individual serves as an officer, director, trustee, general partner, or employee, or which is a prospective employer. Because SGEs often have substantial outside employment and other interests which are often related to the subject areas in which the government seeks their services, issues under Section 208 frequently arise.

COI can arise in many different ways, such as stocks; bonds; interests through ownerships, partnerships, or Limited Liability Corporations (LLCs); consulting arrangements; grants and contracts; and employment. Anything that can financially impact the SGE or the interests of others with whom he or she has a certain relationship can represent a COI. Certain waivers and exceptions to Section 208 are utilized.

The term "particular matter" refers to deliberations, decisions, or actions that are focused upon the interests of specific persons or entities or an identifiable class of persons or entities. The government interprets this term broadly. A particular matter does not extend to broad policy options or considerations directed toward the interest of a large and diverse group of people. A particular matter may involve specific parties, such as a contract, grant, or case in litigation. It may be a particular matter of general applicability that is focused on the interests of a discrete and identifiable class of persons, such as an industry, a group of manufacturers, or healthcare providers.

The distinction between a particular matter of general applicability and one that involves specific parties can be important for SGEs serving on FACA committees, who are covered by certain exceptions from Section 208. The most significant of these exceptions is 5 Code of Federal Regulations (CFR) 2640.203(g), which permits SGEs serving on FACA committees to participate in particular matters of general applicability in which the disqualifying financial interest arises from the SGE's non-federal or prospective employment. This exception is subject to the following limitations:

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SGEs may be granted an individual waiver in which the official responsible for the appointment certifies in writing that the need for the SGE's services outweighs any potential COI posed by the financial issues involved.

For a financial interest in a particular matter to be disqualifying, there must be a direct and predictable effect on the SGE's financial interests. A particular matter will have a direct effect on a financial interest if there is a close causal link between any decision or action to be taken in the matter by the advisory committee and any expected effect on the matter of financial interest.

A particular matter will not have a direct effect on a financial interest if the link is attenuated or reduced, or is contingent upon the occurrence of events that are speculative or are independent of, or unrelated to, the matter. A particular matter that has an effect on a financial interest only as a consequence of its effects on the general economy is also not considered to have a direct effect on a financial interest. A particular matter will have a predictable effect if there is a real, as opposed to speculative, possibility that the matter will affect a financial interest. It is not necessary to know the magnitude of the loss or gain, and the dollar amount is immaterial.

Circumstances related to an SGE's relationships outside the government may lead to questions regarding the appearance of a lack of impartiality; that is, if a reasonable person who is familiar with the facts could question the SGE's impartiality. If ethics officials determine that an SGE's impartiality is likely to questioned, then the ethics officials must decide whether the SGE can participate in a particular matter. CDC may determine that the interests of the government in the SGE's participation outweigh the concern that a reasonable person may question the integrity of the agency's programs and operations.

It is not uncommon for an SGE to want to represent an organization to the government while being employed by the government. For example, an SGE may seek a government grant or contract while being employed as an SGE. The following two COI statutes impose related restrictions on outside activities of SGEs, particularly activities involving the representation of others before the government:

- ☐ 18 United States Code (USC) 203 prohibits federal employees from receiving, agreeing to receive, or soliciting compensation for representational services rendered either personally or by another before any court or federal agency in connection with a particular matter in which the US is a party or has direct and substantial interest.
- ☐ 18 USC 205 prohibits federal employees from personally representing anyone before a court or federal agency in connection with a particular matter in which the US is a party or has a direct and substantial interest. This prohibition applies whether or not the employee receives any compensation for the representational activity. It prohibits federal employees from representing anyone in the prosecution of a claim against the US or from receiving any gratuity, share, or interest in a claim as a consideration.

Both statutes are limited in their application to SGEs. SGEs are only restricted in connection with particular matters that involve specific parties. Such matters typically involve specific proceedings affecting the legal rights of parties, such as contracts, grants, requests for rulings, litigation, or designations. Unlike regular federal employees, SGEs may represent others or receive compensation for representational services in connection with particular matters of general applicability, such as broadly applicable policies, rulemaking proceedings, and legislation, which do not involve specific parties. Restrictions on SGEs are narrowly drawn to focus only on those particular matters in which the SGE at any time participated substantially and personally.

Public service is a public trust. The Standards of Ethical Conduct for Employees of the Executive Branch state that "each employee has a responsibility to the United States Government and its citizens to place loyalty to the Constitution, laws and ethical principles above private gain." In order to ensure that US citizens have complete confidence in the integrity of the government, it is vital that government employees, including SGEs, do not misuse their public position for private gain.

The Standards of Ethical Conduct for Employees of the Executive Branch address the use of nonpublic information. Nonpublic information is any information that an employee receives because federal employment that the employee knows, or reasonably should know, has not been made available to the general public. Government employees may not engage in a financial transaction using nonpublic information or allow the improper use of nonpublic information to further their own private interests or those of another, whether through advice or recommendation or via knowing, unauthorized disclosure. Additionally, government employees have a duty to respect and conserve government property and must not use it or allow its use for other than authorized purposes.

During the term of employment, SGEs may continue to receive fees, honoraria, and other compensation for teaching, speaking, and writing undertaken in their person or non-governmental capacities. SGEs are prohibited from receiving outside compensation for teaching, speaking, or writing about their government duties or any topic if the invitation comes from a person or organization substantially affected by the matters on which they work as an SGE.

Some SGEs are subject to the Emoluments Clause of the US Constitution, which prohibits persons who hold offices of profit or trust in the US Government from having any position in, or receiving any payment, from a foreign government. Most CDC Federal Advisory Committees, including the NCIPC BSC, are exempt from the Emoluments Clause. Like all government employees, SGEs are subject to 5 CFR 2635.202, which prohibits the acceptance of gifts from a "prohibited source" and gifts offered because of an employee's official position. Additionally, like all government employees, SGEs are subject to the criminal bribery and illegal gratuity statue, which prohibits under certain circumstances the receipt of anything of value in connection with their official acts.

The Hatch Act (5 CFR 734) restricts certain political activities of government employees, including SGEs, when they are engaged in government business. They may not engage in partisan political activities, run for political office in a partisan election, or solicit contributions from the public. Further, all government employees, including SGEs, are subject to certain restrictions on personal fundraising for nonprofit organizations. These include restrictions on the use of official title, position and authority, and the solicitation of subordinates.

A government employee may not, other than on behalf of the US, serve as an expert witness with or without compensation, in any proceeding before a court or agency of the US in which the US is a party or has a direct and substantial interest, unless authorized. The prohibition on expert testimony (5 CFR 2635.805) applies to SGEs only if they have participated as government employees in the particular proceeding or in the particular matter that is the subject of the proceeding.

Many of the ethics laws and regulations are straightforward, while others are complex. It is important to contact MASO at CDC with any questions or concerns. NCIPC BSC members can also contact the DFO for additional help. Regarding SGEs, resolving conflicts will ensure that CDC's work is conducted with the highest ethical standards. When government agencies follow high ethical standards, they improve public confidence in their work. CDC makes every effort not only to comply with all of the ethics rules, but also to avoid even the appearance of impropriety. If there is uncertainty regarding what to do in a particular situation, SGEs should get advice from their ethics officials. Working together, we can ensure that the government's business is conducted with impartiality and integrity.

#### **Discussion Points**

Dr. Fowler observed that the burden of information required from SGEs has increased over the years. For instance, the requirement to "unpack" one's entire investment portfolio for the financial disclosure is onerous. Some BSC members feel that they spend more time completing the necessary paperwork than they spend serving NCIPC. She asked why the process has become so much more complex.

Mr. Wheeler answered that several years ago, an Inspector General (IG) investigation admonished CDC for not collecting enough information on the financial disclosure forms. Regarding retirement plans, diversified mutual funds are not reportable and should not be reported.

Dr. Fowler said that the forms ask for full and honest disclosure. If all investments are not reported, then the disclosure will not be complete.

Mr. Wheeler said that if a person reports a 401(k) or an Individual Retirement Account (IRA), then he instructs them that the underlying holdings in the fund must be disclosed unless they are diversified mutual funds. The instructions on the form are not comprehensive.

**Dr. Hamby** said that many SGEs are likely to have retirement funds through TIAA-CREF. They must disclose holdings in the real estate index. The requirements are complicated, as some holdings are required to be disclosed and others are not.

Mr. Wheeler said that if the account names in a TIAA-CREF account are provided, then MASO will be able to determine the underlying holdings, even in real estate accounts or stock accounts. MASO can also determine the holdings of other funds based on their names. Their goal is to assess whether an SGE holds stock on which he or she can have an impact as a committee or board member. Few CDC advisory committees allocate funds, but MASO must determine potential COIs.

Dr. Fowler said that many people are expressing concern about the requirements, which may decrease willingness to participate on FACA committees. Most people do not mind committing a few days a year to the service of a federal advisory committee, but when the paperwork doubles or triples the time commitment, then their decision may be affected. Many SGEs have professional spouses or partners, and it is an extraordinary burden to complete the reports. Further, the instructions are not clear and should be revised.

Mr. Wheeler agreed that the instructions are vague, and MASO is available to work with SGEs and answer their questions. Next year, it will be possible to repopulate the report from the previous year's data and only make necessary changes and updates. Dollar amounts are not required, he reminded the group. Some SGEs provide a broker's statement, which is an acceptable alternative to listing all of the information in the form.

Dr. Allegrante said that the concerns with the financial disclosures are not only about the time burden that they represent, but also about the broader issue of the point at which the "need to know" trumps personal privacy and the right to privacy. At a time when the government in general is being scrutinized for intrusion into personal lives, people have concerns about the level of reporting that is required for these assignments.

- **Dr. Hargarten** added his concerns regarding personal privacy. BSC members were asked to complete 16 different forms and provide their Social Security Numbers six times. The forms represent an unacceptable burden on SGEs who seek to serve the government. The ethics review was a good reminder for them all, but he encouraged MASO to reexamine the process. The number of forms and the repeated information needs to be reviewed so that the process is appropriately balanced for all parties.
- **Dr. Fowler** emphasized that the concerns were not personally directed toward Mr. Wheeler. Streamlining and clarifying the process will be beneficial to MASO to save their time as well.
- **Mr. Wheeler** noted that the financial disclosure forms do not require a Social Security Number. Some personnel forms do require that information, however.
- **Dr. Cattledge** added that the different systems used at CDC and HHS do not "talk to each other". Therefore, the personnel information does not link to the financial disclosure database which is managed by the Department of Defense.
- **Dr. Fowler** observed that one of the privileges of serving on a FACA committee is that their discussions are part of the public record. Their constructive recommendations to improve any part of the system will be helpful.
- **Mr. Wheeler** said that some FACA committees have significant public participation and attendance. For instance, the Advisory Committee on Immunization Practices (ACIP) attracts a great deal of public scrutiny.
- **Dr. Molock** said that she has a number of IRAs, because she has worked at different institutions, and it was difficult to provide all of the required information for each one. Further, she serves on a National Task Force and recently completed a clearance for that position. She wondered why she had to complete some of the same forms again for the BSC.
- **Mr. Wheeler** agreed and noted that many BSC members complete similar forms for their institutions. CDC uses a different system, however. MASO uses FDM for financial disclosure, but the CDC Ethics Program uses a different system. The forms do not "mesh" within CDC.
- **Dr. Mickalide** asked whether these issues and requirements could be disclosed to individuals when they are invited to serve on a FACA committee in order to reduce burden on everyone. Completing the forms required approximately three days of work. Individuals should have the option to make an informed decision regarding whether or not they will serve.
- **Dr. Fowler** said that she had asked about completing some of the orientation requirements before appointment. Further, the orientation could be conducted more efficiently, perhaps via a web-based format. The process for applying to serve on a committee does not make many of these requirements clear.
- **Dr. Porucznik** added that the application process was a year long, so people may not remember information that was shared with them at the beginning of the process.
- **Dr. Cattledge** said that nominees are not submitted individually, but as a complete package. There were delays due to the Presidential election in 2012. She suggested that she and Mr. Wheeler share these comments with HHS Committee Management.

**Mr. Wheeler** said that SGEs are asked to submit a Foreign Activities Questionnaire to HHS every year. It may be possible to combine that questionnaire into the financial disclosure report.

**Dr. Molock** wondered whether forms for instructions or travel could be included as attachments to emails. They would be easier to find as attachments than imbedded within emails.

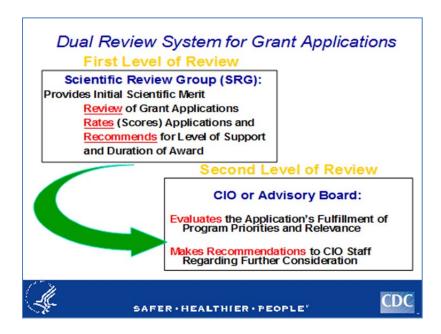
**Dr. Cattledge** said that the secure BSC website can serve as a resource for that information.

**Dr. Hargarten** observed that these problems cannot be unique to CDC. Other agencies in which individuals serve in similar fashions address uniform ethics issues, and the disclosure requirements are likely to be similar as well. He wondered whether the process could be codified more uniformly so that academic institutions can assist and position the individuals to satisfy the requirements. Well-intentioned people are discouraged from serving.

#### **ERPO / Peer Review Orientation**

Christine Morrison, PhD
Director, Extramural Research Program Office
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

**Dr. Morrison** thanked the BSC for participating in the important secondary review process. She explained that the secondary review does not discuss the scientific and technical merit of the applications. The primary peer review panel engaged in these discussions in May 2013. The primary review panel placed the applications in rank order based on scientific merit, and then CDC staff made recommendations. The following diagram illustrates the dual review system for grant applications to CDC:



The primary review includes review and discussion of the applications by scientific experts. Three reviewers critique each application and present their critiques to the rest of the panel. The background and specialty of each reviewer is matched to the application that he or she reviews. Their backgrounds also help them articulate the strengths and weaknesses of the applications clearly. The entire panel then votes on each application based on the discussion. Initial scores provided by the reviewers can change. A summary statement is generated based on the panel discussion and a compilation of the critiques, particularly the strengths and weaknesses, from the three reviewers. The resume portion of the summary statement includes the most salient points from the discussion and the "score-driving" issues that are raised.

Neither the primary nor the secondary review panel makes funding decisions. The rank order scores reflect the scientific merit of the applications as determined by the primary peer review panel. The secondary review then assesses the relevance of the applications to the NCIPC research priorities and program balance and recommends to the NCIPC Director and staff which applications should be funded and the scorable range for funding, should additional resources become available. Even though funding is only available for three awards, "miracles sometimes happen," and it can be possible to fund more projects. The NCIPC Director makes the final funding decisions.

The staff analysis includes the background, purpose and importance of research solicited in the FOA; the funds available; a synopsis of the initial scientific merit review process; and the applications that are recommended for funding by CDC staff. Staff from the NCIPC division supporting the FOA and from the Extramural Research Program Office (ERPO) consult to create that analysis.

The primary review panel scores applications on a range from 1 to 9, with one being the best and 9 being the worst. The scoring calibration guide is divided into three categories for impact: High, Medium, and Low. A score of 1-3 is High Impact, a score of 4-6 is Medium Impact, and a score of 7-9 is Low Impact. Descriptors are assigned to each score as follows:

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
	1	Exceptional	Exceptionally strong with essentially no weaknesses
High	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
	4	Very Good	Strong but with numerous minor weaknesses
Medium	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
	7	Fair	Some strengths but with at least one major weakness
Low	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses
Minor VVea	ikness: An easi	Ily addressable weakness	s that does not substantially lessen impact

The weaknesses are defined as follows:

Minor Weakness: An easily addressable weakness that does not substantially lessen
impact.
Moderate Weakness: A weakness that lessens impact.
Major Weakness: A weakness that severely limits impact.

Funding is dependent upon the overall impact score. Individual scores are assigned for different criteria, such as significance, investigators, innovation, approach, and environment. The overall impact score reflects how the application will move the field forward. The individual criterion scores have an impact on the overall score, but the overall score does not represent an average of the criterion scores. CDC multiplies the overall impact scores by 10.

Typically, the BSC Chair serves as Chair of the secondary review. Because of a conflict, however, Dr. Morrison pointed out that Dr. Fowler would recuse herself from the secondary review to be conducted during this BSC meeting. The secondary review chair leads the meeting and facilitates it with the assistance of the ERPO Director and the Scientific Program Officer (SPO). The ERPO Director and NCIPC Deputy Associate Director for Science (ADS) organize the meeting and, with other relevant staff, serve as a resource for panel members.

Meeting procedures include a review of COI and confidentiality by the ERPO Director, an overview of the FOA and staff recommendations by the SPO; and Discussion and voting by the secondary review panel.

If the secondary panel decides not to fund the applications in rank order, but two or more members of the panel support funding the applications in rank order, then a Minority Report must be completed, in which the dissenting panel members articulate why they support funding the applications in rank order. The Funding Recommendation Sheet includes which applications will be funded and the level at which funding will be "cut off." Signed original copies of the sheets should be provided to the ERPO Director.

#### **Discussion Points**

In response to a question from **Dr. Mickalide**, **Dr. Morrison** clarified that although \$1.05 million is available for this announcement and ERPO anticipates awarding \$350,000 to three applicants, they are not compelled to award all of the funds that are available.

**Dr. Fowler** noted that she has been on BSCs that have recommended not to fund applications. In the past, the BSC has been concerned about scientific merit, even though the secondary review does not evaluate scientific merit.

**Dr. Morrison** added that there are differing opinions about what a score means. The NIH table lists descriptors for scores, especially given that people score differently, and the scores should match the descriptors. NIH also changed its numbering system from 1 to 5 to 1 to 9. The expansion was instituted in hopes that the scores would "spread out," but that has not been the case.

**Dr. Hamby** asked how sequestration would affect the available funding.

**Dr. Morrison** replied that this R01 will be reduced. The decision is not final, but two of the awards may be for \$330,000 and one will be for \$325,000. They still hope that the awards will be sizable.

**Dr. Mickalide** asked about instances in which the secondary review panel does not see all of the applications because CDC staff or the primary panel does not consider them to be meritorious.

**Dr. Morrison** answered that before the applications are sent to the peer review, they undergo a responsiveness review. The FOA is specific regarding the requirements in order for an application to be considered responsive. The applications' responsiveness is evaluated by CDC's Procurement and Grants Office (PGO), the Grants Management Specialists, and the SMEs in the division. Many applications under this FOA did not address primary prevention and were therefore deemed non-responsive and not sent to primary peer review. Usually, the average of the preliminary scores from the three reviewers is used to determine the upper half of all applications that are scored. In this case, however, the panel assigned diverse scores to the applications. For instance, if an application receives scores of 5, 1, and 3, then it is not clear whether the application is strong, so it is reviewed.

**Dr. Mickalide** asked whether ERPO provides the summary statements to the BSC for secondary review.

**Dr. Morrison** answered that ERPO provides the summary statements to persons who are not in conflict with the review. The ideal way to review the summary statements is to view them online via the Internet-Assisted Review (IAR) system. Internet access is available for the primary review panel during the review.

**Dr. Molock** asked to be informed in advance whether WiFi access would be available for meetings.

**Dr. Cattledge** said that past BSC members have printed their materials and brought them to the meeting.

**Dr. Fowler** agreed that some reviewers will be more "tough" than others. She noted that the new scale of 1 to 9 has not resulted in a wider range of scores. She asked about efforts to learn about who scores high, and who scores low. The Injury Control Research Centers (ICRCs) will be reviewed soon. Funding decisions can rest on very small differences in scores. It is alarming to think that applications may not be funded based on one or two reviewers.

**Dr. Morrison** replied that ERPO emphasizes in pre-review calls that reviewers should spread their scores across the entire range. However, the tendency is to "make things better." There have been concerns regarding fairness and scoring among panels in the past. On average, the scores are similar, however. The standard deviation is very little. The overall trend has been a "score creep" upward.

**Dr. Fowler** encouraged Dr. Morrison and ERPO to continue to work toward a greater scoring spread, especially as funding gets tighter.

**Dr. Gorman-Smith** observed that this problem exists across other federal agencies as well. NIH is revising its review process again.

Dr. Morrison said that CDC uses the NIH protocol because so many of CDC's reviewers also review for NIH.

**Dr. Fowler** said that the injury and violence prevention community is tight-knit and collaborative. For many funding opportunities such as the ICRCs, it may be nearly impossible to build a primary review committee that is comprised of people who know enough about the field and the realities of serving as a center who will not have a conflict with the applicants. Concern has been expressed regarding a complex construct such as the ICRCs that is reviewed by people who do not understand it fully.

**Dr. Morrison** agreed that this issue represents a flaw in the system. In order to be completely objective, they endeavor to match the reviewers' expertise to the applications as best they can. The BSC could not be used as the secondary panel for the ICRCs, for instance, because of the large number of conflicts. ERPO convened a Special Emphasis Panel (SEP) for the ICRCs, with Dr. John Borkowski serving as the chair. It was challenging to populate the panel with individuals who had adequate expertise and no conflicts with the applications. They are open to solutions and suggestions to help address this problem.

Dr. Gorman-Smith agreed that this perception problem exists for ICRCs, Academic Centers of Excellence (ACEs), and other entities. She has spoken with a number of people who should apply for CDC funds but who do not because of the review process. They feel that panels do not have sufficient expertise to give fair reviews.

Dr. Morrison answered that her first "baptism by fire" as ERPO Director was to coordinate an ICRC review. The ICRC structure includes an Administrative Core, Training and Education Core, Outreach Core, and three to four research projects. Assigning three reviewers to such a complex application was a problem. Her approach was to assign at least 12 reviewers per application. Each of the research projects was reviewed by three independent reviewers with relevant expertise. Each of the three cores was also reviewed by three separate reviewers. There were few complaints about that approach. They have gone to great lengths to do the best that they can within the system that they have.

**Dr. Mickalide** asked whether BSC members are not eligible to participate in a primary peer review during their term on the BSC.

Dr. Cattledge said that traditionally, individuals who serve on the BSC and participate in the secondary review do not serve as primary reviewers during the initial scientific peer review of submitted applications. The same person should not participate in both parts of the review process. Dr. Hamby said that she was scheduled to serve as a primary reviewer, but she was removed from the panel, after she was appointed to the BSC.

Dr. Morrison agreed that MASO does not approve dual service. It is not permissible to advise the government more than once. Individuals who participate on an NIH panel cannot participate in a CDC panel at the same time.

Dr. Hamby asked if BSC members cannot sit on any review panels for the government while they are on the BSC. Dr. Gorman-Smith said that she recently served on an NIH panel. Dr. Cattledge clarified that Dr. Gorman-Smith was serving as an ad hoc member, not on an appointed advisory board member.

- **Dr. Morrison** said that NIH has different regulations. CDC's MASO office is strict about dual service. The selection of reviewers is also constrained by requirements for geographic, racial, and public / private distribution.
- **Dr. Hamby** asked about SEPs at other institutions. **Dr. Morrison** answered that CDC's MASO would not allow a BSC member to participate on a CDC SEP.
- **Dr. Cattledge** replied that BSC members have participated as SEPs for NIH, because they are ad hoc members and are not serving as sitting board members. **Dr. Morrison** noted that an SEP is one-time service. There may be a problem if the service is concurrent.
- **Dr. Molock** is on a National Task Force with the National Institute of Mental Health (NIMH) and wondered whether her service on that task force is precluded by her service on the NCIPC BSC. **Dr. Cattledge** answered that MASO reviewed Dr. Molock's other appointments and conflicts, so her participation on both were not considered a conflict.
- **Dr. Fowler** expressed concern about the dramatically decreasing number of FOAs that are released. She wondered how NCIPC can increase the number of FOAs, especially in the area of unintentional injury. The BSC used to receive progress reports on the applications, and she asked to receive updates regarding which applications are funded, and at what level.
- **Dr. Morrison** answered that in her year at ERPO, all of the BSC recommendations have been approved and all of the applications have been funded. No additional funds have become available. Dr. Degutis is very supportive of the primary review panel, and she believes strongly that scientific merit should drive funding decisions.
- **Dr. Fowler** said that it would be helpful to understand the purpose of the secondary review process. They have not often disagreed, but the purpose of the process is not clear if it has no impact on the initial decision.
- **Dr. Morrison** replied that in her tenure, the secondary panel has not disagreed with the conclusions of the scientific merit scores of the primary review panel. She offered to share the list of the applications that were funded. Regarding unintentional injury, FOAs pertaining to motor vehicle injury, prescription drug overdose, and TBI are coming offline soon. In intentional injury, the FOAs focus on sexual violence and child maltreatment.
- **Dr. Fowler** asked about strategic thinking regarding whether funds are available for other kinds of research that could be compatible with injury-related outcomes. For example, work on walkable communities and issues concerning community safety and chronic disease could provide opportunities for partnerships that could allow for creative funding.
- **Dr. Morrison** replied that she and Dr. Degutis have a meeting scheduled with the NCIPC division directors to consider creative ways to extend their reach. Partnerships will be part of that discussion, as well as innovative changes to their existing programs. The addition of developmental centers to the ICRCs represents a change that NCIPC hopes will grow the field and extend their reach. They cannot lobby, and their grantees cannot lobby with CDC money, but the availability of funds is the driver of the number of FOAs that are released. There is a general feeling that extramural work is not as important as intramural, and that working with states and programs will have more impact. This culture embraces the idea that new research is not needed as much as the existing evidence base needs to be applied.

**Dr. Feucht** asked about the role of BSC *ex officio* members in the secondary review. **Dr. Cattledge** answered that BSC *ex officios* help identify where there may be duplication of efforts. In the past, *ex officios* have also identified instances in which an applicant has applied to two different agencies with the identical project. Federal liaisons share their work and discuss potential for future collaborations, especially regarding funding FOAs. **Dr. Feucht** said that the federal liaisons are very willing to help in that regard.

There was discussion regarding materials that some BSC members and *ex officios* were not able to access in IAR.

**Dr. Hamby** returned to the issues of the over prevalence of high scores and of inexperienced reviewers. These two issues are related. By random chance, three inexperienced reviewers can be assigned to the same application and score it too high, and a stronger proposal can be reviewed by three experienced reviewers who do not score as generously. Regarding people in the field not wanting to apply for CDC funding, she noted that many of the CDC projects are one-time, special emphasis projects without an opportunity to resubmit, as NIH has. Not having this opportunity may discourage people from applying to CDC.

**Dr. Morrison** said that the nature of the FOAs is not in NCIPC's control. She stressed that although they are under many constraints regarding reviewers, in her experience, it is rare to see three inexperienced reviewers assigned to an application. The whole panel, not just the three reviewers, scores the applications. There have been cases in which a reviewer has assigned an inflated score and an experienced reviewer has teased out the reasons behind the score. Panel members have the option to score outside the range of the three reviewers and add a comment to their score sheets explaining why.

**Dr. Hamby** agreed but noted that people are often not willing to move their scores by much. If there is pressure not to score outside the range, then they are even less willing to do so.

**Dr. Morrison** assured them that staff are careful to avoid those situations and will interrupt if needed.

#### **Secondary Review Closed to the Public**

Upon establishing a quorum, the meeting was closed to the public in order to process with the secondary review. During this session, a secondary review was conducted on the following NCIPC Funding Opportunity Announcement (FOA), FOA CE13-002, "Research Grants for Preventing Violence and Violence-Related Injury". Following the discussion and voting process, the meeting was adjourned after the wrap-up session.

## Wrap-Up, Roll Call, and Adjourn

Carolyn J. Cumpsty Fowler, PhD, MPH
Chair, National Center for Injury Prevention and Control Board of Scientific Counselors
Assistant Professor, Johns Hopkins University
School of Nursing and Bloomberg School of Public Health

**Dr. Cattledge** thanked the BSC for their time and commented on their rapport, and emphasized that she looked forward to working with them in the coming months.

**Dr. Porucznik** suggested that it would be efficient to plan a BSC meeting in conjunction with the World Injury Conference in Atlanta in 2014. **Dr. Fowler** said that NCIPC was working to return to a schedule of regular BSC meetings in the spring and fall. **Dr. Harris** thought that such a move would help with planning.

**Dr. Fowler** summarized the BSC's discussion during the morning session. There was discussion regarding the challenges associated with appointment to the BSC, including the volume of paperwork and disclosure regarding rules and regulations regarding BSC membership before a member joins the body. Members of the BSC have agreed to sign a letter to Elaine Baker detailing their concerns about the committee appointment process and suggesting ways that the process can be streamlined to ease the burden on CDC staff and BSC members. Dr. Fowler will write, on behalf of the BSC, a letter to Dr. Degutis describing ideas for how the body can be used more effectively. She reminded the BSC members on the telephone to send an email to Ms. Lindley confirming their participation, thanked the NCIPC staff and contractors who made the meeting possible, and officially adjourned the meeting at 12:42 pm.

#### Certification

I hereby certify that to the best of my k NCIPC BSC meeting are accurate and	nowledge, the foregoing minutes of the June 14, 2013 complete:
Date	Carolyn Cumpsty Fowler, PhD, MPH Chair, NCIPC BSC

#### **Attachment A: Meeting Participants**

#### **BSC Members**

- John Allegrante, Ph.D
- John Borkowski, Ph.D
- Carolyn J. Crumpsty Fowler, Ph.D. M.P.H.
- Sherry Hamby, Ph.D.
- Stephen Hargarten, Ph.D.
- Robert Harris, M.D.
- Angela Mickalide, Ph.D. MCHES
- Sherry D. Molock, Ph.D.
- Maury Nation, Ph.D
- Christina Porucznik, Ph.D
- Maria Testa, Ph.D
- Shelly Timmons, M.D.

#### Federal Liaisons Present (Via Teleconference)

- David R. Boyd, MDCM, FACS, National Trauma Systems Coordinator, Office of Emergency Services, Indian Health Service
- Lisa J. Colpe, PhD, MPH, Chief, Office of Clinical and Population Epidemiology Research, Division of Services and Intervention Research, National Institute of Mental Health
- Elizabeth A. Edgerton, MD, MPH, Branch Chief, EMSC and Injury Prevention, Maternal and Child Health Bureau, Health Resources and Services Administration
- Thomas E. Feucht, PhD, Executive Senior Science Advisor, National Institute of Justice
- Jane L. Pearson, PhD, Associate Director for Preventive Interventions, Division of Services and Intervention Research, National Institute of Mental Health
- Farris K. Tuma, ScD, Chief, Traumatic Distress Disorders Research Program, Division of Adult Translational Research and Treatment Development, National Institute of Mental Health

#### **CDC Staff**

- Gwendolyn H. Cattledge, PhD, MSEH, FACE
- Linda Dahlberg, Ph.D.
- Demetria Gardner
- Daniel Holcomb
- Tonia Lindley
- Paul Smutz. PhD
- David G. Williamson, Ph.D.
- Terry Wheeler

### **Others Present / Affiliations**

- Sydney S. Vranna, Conference Planner, Seamon Corporation
- Kendra Cox, Writer / Editor, Cambridge Communications & Training Institute
- Jim Evans, AV, Sound on Site
- Stephanie Henry-Wallace, Writer / Editor, Cambridge Communications & Training Institute

# **Attachment B: Acronyms Used in this Document**

Acronym			
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ACE	Academic Center of Excellence		
ACIP	Advisory Committee on Immunization Practices		
ADS Associate Director for Science			
BSC	Board of Scientific Counselors		
CDC	Centers for Disease Control and Prevention		
CFR	Code of Federal Regulations		
COI	Conflict of Interest		
CV	curriculum vita		
DFO	Designated Federal Officer		
DOE	(United States) Department of Energy		
ERPO	7 1 07		
FACA	Federal Advisory Committee Act		
FDM	Army Financial Disclosure Management System		
FOA	Funding Opportunity Announcement		
GSA	General Services Administration		
HHS	(United States Department of) Health and Human Services		
IAR	Internet-Assisted Review		
ICRC	Injury Control Research Center		
IG	Inspector General		
IPV	Intimate Partner Violence		
IRA	Individual Retirement Account		
LLC	Limited Liability Corporation		
MASO	Management Analysis and Services Office		
NARA	National Archives and Records Administration		
NCEH	National Center for Environmental Health		
NCIPC	National Center for Injury Prevention and Control		
NGO	Non-Governmental Organization		
NICHD	National Institute of Child Health and Human Development		
NIH	National Institutes of Health		
NIMH	National Institute of Mental Health		
OGE	Office of Government Ethics		
PGO	Procurement and Grants Office		
PI	Principal Investigator		
SEP	Special Emphasis Panel		
SGE	Special Government Employee		
SME	Subject Matter Expert		
SPO	Scientific Program Officer		
SV	Sexual Violence		
USC	United States Code		